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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,304	03/10/2004	Jurgen Rohr	50229-429	9088

EXAMINER
SWARTZ, RODNEY P

ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
06/14/2007	PAPER

7590 06/14/2007
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Washington, DC 20005-3096

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/796,304	Applicant(s) ROHR ET AL.	
	Examiner Rodney P. Swartz, Ph.D.	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) 11-47 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-10 is/are allowed.
- 6) ☒ Claim(s) 48 and 49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-49 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>1/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicants' Response to Restriction Requirement, received 21 March 2007, is acknowledged. Applicants elect, without traverse, Invention I, claims 1-10, 48, 49, drawn to compound, classified in class 424, subclass 234.1. Applicants also elect, without traverse, the species set forth in claim 10.

Claims 1-49 are pending. Claims 11-47 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

2. Claims 1-10, 48, and 49 are under consideration.

Specification

3. The disclosure is objected to because of the following informalities:

Paragraph 0002, line 2, the provisional application number must be added.

Paragraph 0012, delete the period immediately following *Streptomyces*

Paragraph 0028, the first sentence has no verb.

Paragraph 0037, line 3, "*argillaceus*" should be "*S. argillaceus*"; paragraph 0040, line 2, "20/μg/mL" should be "20 μg/mL".

Amended Paragraph 0045, line 1, "numbers are X01385" should be "numbers X01385"; line 2, the amended form indicates simultaneous deletion and insertion, i.e., 56, thus the paragraph reads, "set forth in Fig. as".

Paragraph 0051, line 1, "anoalog" should be "analog".

Paragraph 0065, next to last line, what is meant by "anticity"?

Paragraph 0066, last line, "single does" should be "single dose".

Paragraph 0077, line 1 to 2, "in subject diagnose" should be "in a subject diagnosed".

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Abstract, lines 2 and 4, "argillaceous" should be "argillaceus" to be consistent with the rest of the specification.

Appropriate correction is required.

Budapest Treaty Requirements

4. The specification lacks complete deposit information for the deposit of *S. argillaceus*, M7WI. Because it is not clear that other mutant bacteria possessing the properties of *S. argillaceus*, M7WI are known and publicly available or can be reproducibly isolated from nature without undue experimentation and because the best mode disclosed by the specification requires the use of *S. argillaceus*, M7WI for the production of the claimed compounds, a suitable deposit for patent purposes is required. Without a publicly available deposit of the above *S. argillaceus*, M7WI, one of skill in the art could not be assured of the ability to practice the invention as claimed. Exact replication of the *S. argillaceus*, M7WI is an unpredictable event. Note that the best mode is not satisfied by a written disclosure unless the exact embodiment is reasonably reproducible from that disclosure. If reproducibility of the *S. argillaceus*, M7WI is not established, failure to deposit *S. argillaceus*, M7WI would result in concealment of the best mode contemplated by applicant for carrying out the invention. In re Sherwood, 615.2d 809, 204 USPQ 537 (CCPA 1980).

Applicant's referral to the deposit of the parent strain of *S. argillaceus*, M7WI on page 1 of the specification is an insufficient assurance that all required deposits have been made and all the conditions of 37 CFR §§1.801-1.809 have been met.

If the deposit has been made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicant or assignees or a statement by an attorney of record who has authority and control over the conditions of deposit over his or her signature and registration number stating that the deposit has been accepted by an International Depository Authority under the provisions of the Budapest treaty, that all restrictions upon public access to the deposit will be irrevocably removed upon the grant of a patent on this application and that the deposit will be replaced if viable samples cannot be dispensed by the depository is required. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each nation. Amendment of

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the specification to recite the date of deposit and the complete name and full street address of the depository is required.

If the deposits have not been made under the provisions of the Budapest treaty, then in order to certify that the deposits comply with the criteria set forth in 37 CFR §§1.801-1.809, assurances regarding availability and permanency of deposits are required. Such assurance may be in the form of an affidavit or declaration by applicants or assignees or in the form of a statement by an attorney of record who has the authority and control over the conditions of deposit over his or her signature and registration number averring:

- a) during the pendency of this application, access to the deposits will be afforded to the Commissioner upon request;

- b) all restrictions upon the availability to the public of the deposited biological material will be irrevocably removed upon the granting of a patent on this application;

- c) the deposits will be maintained in a public depository for a period of at least thirty years from the date of deposit or for the enforceable life of the patent or for a period of five years after the date of the most recent request for the furnishing of a sample of the deposited biological material, whichever is longest; and

- d) the deposits will be replaced if they should become nonviable or non-replicable.

In addition, a deposit of biological material that is capable of self-replication either directly or indirectly must be viable at the time of deposit and during the term of deposit. Viability may be tested by the depository. The test must conclude only that the deposited material is capable of reproduction. A viability statement for each deposit of a biological material not made under the Budapest Treaty must be filed in the application and must contain:

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- 1) the name and address of the depository,
- 2) the name and address of the depositor,
- 3) the date of deposit,
- 4) the identity of the deposit and the accession number given by the depository,
- 5) the date of the viability test,
- 6) the procedures used to obtain a sample if the test is not done by the depository, and
- 7) a statement that the deposit is capable of reproduction.

As a possible means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If the deposit was made after the effective filing date of the application for patent in the United States, a verified statement is required from a person in a position to corroborate that the *S. argillaceus*, M7WI described in the specification as filed is the same as that deposited in the depository. Corroboration may take the form of a showing of a chain of custody from applicant to the depository coupled with corroboration that the deposit is identical to the biological material described in the specification and in the applicant's possession at the time the application was filed.

Applicant's attention is directed to *In re Lundeck*, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985) and 37 CFR §§1.801-1.809 for further information concerning deposit practice.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 48 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is drawn to a particular mutant *Streptomyces argillaceus*, namely M7W1, which produces a particular compound. The sole designation of "M7W1" is merely a laboratory designation, and as such is indefinite. It is recommended that the mutant be designated also by its ATCC number.

7. Claim 49 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for specific compounds listed in claims 1 and 6-10, does not reasonably provide enablement for pharmaceutical compositions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The instant claims are drawn to a "pharmaceutical" composition.

M.P.E.P. §2164.01(c), paragraph 3, recites:

When a compound or composition claim is limited by a particular use, enablement of that claim should be evaluated based on that limitation. See *in re Vaeck*, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991).

Steadman's Medical Dictionary (26th Edition, 1995) defines "pharmaceutical" as "relating to pharmacy or to pharmaceuticals"; "pharmacy" as "the practice of preparing and dispensing drugs", and "drug" as "Therapeutic agent; any substance, other than food, used in the prevention, diagnosis, alleviation, treatment, or cure of disease"

While the definition of "pharmaceutical" is broad, it is not so broad to cover any use of a substance on or in the body of a subject, only those uses intended to prevent, diagnose, alleviate, treat, or cure a disease within the animal to which the substance was administered.

In the instant application, the claimed composition has not administered to prevent, diagnose, alleviate, treat, or cure a disease within an animal. In addition, the instant specification does not teach how to use the composition, without undue experimentation, for the prevention, diagnosis, alleviation, treatment, or cure of a disease in the animal to which the substance is administered.

Conclusion

8. Claims 48 and 49 are rejected. Claims 1-10 appear to be allowable. Claims 11-47 remain withdrawn from consideration.

9. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 7:30 PM EST.


If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Jeffrey Siew, can be reached on (571)272-0787.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


RODNEY P. SWARTZ, PH.D.
PRIMARY EXAMINER
Art Unit 1645

June 9, 2007